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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,631	02/15/2001	Jose A. Fernandez-Pol	42108.0106	2674

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EXAMINER
COPPINS, JANET L

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,631	FERNANDEZ-POL, JOSE A.	
	Examin r	Art Unit	
	Janet Coppins	1625	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 13-83 pending in the instant application.

The Office acknowledges receipt of Applicant's response and Amendment A, filed May 13, 2002, which papers have been placed of record in file.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the Transmittal, while identifying the instant application as a Continuing Application, fails to lay claim to prior application No. 09/127,620, filed 08/01/98, see page 1 of Transmittal.

The Applicant's right to claim benefit of 35 U.S.C. 119(e)/120 to a provisional or to a prior application is based on continuity in the lineage and pendency of cases. Therefore, priority has not been perfected. If Applicant intends to claim priority to said application a new Oath/ Declaration is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(a) Claims 13,18,21,39,43,47,48,53,54,58,59,63,69,70,74,75,78,79, and 83 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The Applicant claims

"A peptide of sixteen amino acids," which is critical or essential to the practice of the invention, but said amino acids are not included in the claims and are not enabled by the disclosure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In order to practice the claimed invention, one skilled in the art would have to screen numerous peptides to see which ones would work for the purposes stated in the present invention. However, the plethora of peptides, thousands of possible combinations and sub combinations, embraced by the terminologies used in the claims (i.e. "a peptide of sixteen amino acids," which reads so broad to be virtually meaningless) which have to be screened imposes undue experimentation on the skilled art worker. There is no absolute predictability even in view of the seemingly high level of skill in the art. Therefore, the broad terminology indicated above, "a peptide of sixteen amino acids," is not enabled. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

(b) Claims 13,18,21,39,43,47,48,53,54,58,59,63,69,70,74,75,78,79, and 83 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Applicant claims "A peptide of sixteen amino acids" without listing the desired acids or any sequences, or providing an empirical arrangements of the acids. Further, the intent of the inventor cannot be ascertained, and the divergence in scope of the possible amino acids could affect the properties of the final products.

(c) Claims 13,18,21, 39 rejected under 35 U.S.C. 112, first agraph, because the specification, while being enabling for treating certain viruses, does not reasonably provide enablement for the treatment of all diseases associated with decreased immune function. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming a metal chelating agent and method of treating a disease, disorder, or condition associated with decreased immune function. The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give any guidance as to the full range of diseases, disorders, or conditions which could be treated or prevented using the instant claimed metal chelating agent. In order to practice the claimed invention, one skilled in the art must speculate which disease could be treated using the agent found in the instant claims. The number of possible diseases or disorders embraced by decreased immune function would impose undue experimentation on the skilled art worker. Therefore, the

broad terminology "treatment of a disease, disorder, or condition selected from the group consisting of...decreased immune function" is not enabled because the metes and bounds of the diseases which could be treated or prevented using the picolinic acid derivatives found in the instant claims cannot be ascertained.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(a) Claims 13-47 and 59-83 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-20 and 59- 64 provide "an agent for the treatment of" in line 1. This phrase renders the claim indefinite because it is unclear whether the applicant is intending to encompass a composition or method/process claim.

(b) Claims 65-69 provide "a preparation for the control of..." in line 1, but, this phrase renders the claim indefinite because it is unclear whether the applicant is intending to encompass a composition or method/process claim.

(c) Claims 21- 42 provide "a method for the treatment of ...comprising a ...chelating agent..." in line 1, but, this phrase renders the claim indefinite because it is unclear whether the applicant is intending to encompass a product/ composition or method/ process claim.

(d) Claims 43-47 provide "(an) agent and a pharmacologically acceptable route of administration" in line 1, but this phrase renders the claim indefinite because it is unclear whether the claims indicate a pharmaceutical composition or a product, and in addition, acceptable methods for routes of administration are not described. Many routes of administration are possible in the art, including oral, rectal, IV, transdermal, intranasal, etc.,

specifically, a composition classified as pharmacologically acceptable in one route, i.e. IV, is not necessarily pharmacologically acceptable as another route, i.e. oral. Therefore it is unclear whether the applicant is intending to encompass a product/composition or method/process claim, and said claims are indefinite as to the route of administration.

(e) Claims 70 and 74, provide "a lavage comprising up to about 99%..." which is vague and indefinite. This phrase reads on 0%, therefore if the ingredients such as a metal chelating agent is not present, then it is unclear whether there is a utility for the said product.

(f) Claims 75 and 78 provide a "preservative comprising less than about 0.025%..." which is vague and indefinite, for the same reasons as provided supra.

(g) Claims 79, 81, and 83 employ the term "contacting" in line 1, rendering the claims indefinite, as it is unclear if the two ingredients are physically contacted with each other or it they are reacted together thus causing a chemical reaction.

(h) Claims 71-73, 76, 77, 80, and 82 are rejected under 35 U.S.C. 112, as being dependent on rejected indefinite base claims.

(i) Claims 13,18,21,39,43,47,48,53,54,58,59,63,69,70,74,75,78,79, and 83 recite the phrase "a peptide of sixteen amino acids..." in the aforementioned claims are inoperative terms which render the claims indefinite. The "sixteen amino acids" which could be ascertained and combined to form the peptide are not listed or defined by the claims. The specification does not provide a list of acceptable amino acids, or any amino acid sequences, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 13-22, 24, 28-30, 32-34,38-40, 43-74, in part, rejected under 35 U.S.C. 102(b) as being anticipated by Otsu et al., US No. 5,582,817. Otsu et al. teach picolinic acids according to formula I, and zinc salts and derivatives according to said formula, which read on the instant claimed metal chelating agent (see page 6). Otsu et al. also disclose preparations of the aforementioned compounds comprising a pharmaceutically acceptable isotonic agent or carrier such as saline. Otsu. et al. teach pharmaceutical compositions of zinc picolinates, wherein said compound is incorporated at a range of about 1-100% or .01 mM to 75 mM by weight, and can be formulated in both oral and non-oral preparations such as capsules, lotions, and inhalant sprays (see page 8). Further the 817 patent describes the use of zinc picolinates as pharmaceutical agents for the treatment of various skin diseases associated with inflammation, including sunburn (see page 7).

6. Claims 18, 20, and 39-43 in part, rejected under 35 U.S.C. 102(b) as being anticipated by Sherlock et al., US No. 4,138,488. Sherlock et al. disclose picolinic acids according to structural formula I, which read on the instant claimed metal chelating agent, see page 2. Sherlock et al. teach the use of said compounds in pharmaceutically acceptable compositions, which are effective antibacterial agents, see page 9. The 488 patent also discloses administering the compound in the form of lotions, creams, aerosols, and ointments, particularly for the treatment of acne, see page 9.

17. It is noted that Applicant has cancelled original claims 1-12 and has added new claims 13-83 in Amendment A. New claims 13-83 incorporate structures and subject matter which are not recited in the original claims, and which fall outside the scope of the original claims. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Coppins whose telephone number is 703.308.4422. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703.308.4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9306 for regular communications and 703.872.9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1235.

JLC
July 2, 2002

Alan L Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
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